

AMENDMENT

U.S. Appln. No. 09/230,137

2386-1-001

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the above amendments and the following remarks. Claims 1-25 and 27-31 remain pending herein. Claim 1 has been amended and it is respectfully submitted that at least page 15, lines 7-11 provide support for this amendment.

Applicant notes with appreciation the indication in the Final Office Action that all grounds of rejection under 35 U.S.C. §112 have been overcome.

Claims 1-25 and 27-31 stand finally rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ostrup (U.S. 5,460,057) in view of Sangha (U.S. 5,334,502). Applicant respectfully traverses and requests reconsideration of this ground of rejection.

Claim 1 has been amended to recite that the sample deposition portion, which is wetted by a fluid sample, is attached to a channel portion, the channel portion having an indicator means arranged at a predetermined lateral distance away from the sample deposition portion, said indicator means indicating that the sample portion is entirely wetted so as to be used for testing; wherein the positioning of the sample to be tested on said sample deposition portion of said supportive material results in excess

AMENDMENT

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2386-1-001

fluid of said sample travelling along said channel portion and interacting with said indicator means to indicate that said sample deposition portion has been entirely wetted by the fluid sample so as to permit the excess fluid to travel along the channel portion and interact with the indicator means. Applicant respectfully submits that the specification at least at page 15, lines 7-11 provide support for this claimed feature.

Applicant respectfully submits that the presently claimed invention is directed to a test device for use in mass screening, particularly where samples can be collected from a patient at a site remote from the test site, and the prior art problems of judging the adequacy of the deposition on a sampler (typically a type of absorbent paper) by eye, or using a camera, neither of which provide a practical means for remote collection, which may be performed by the patient, and/or someone with little medical training.

In fact, in the prior art, before a sample could be "punched out" by a machine, either the judgement of a human operator, or a machine, was required to identify where the best concentration of a sample could be found on the absorbent paper because only a small portion of the sample was punched out. Thus, there was great

inefficiency in determining which portion of the sample to punch out from an entire sample collection area.

In contrast, in the presently claimed invention, the indicator means indicates that the sample deposition portion has been adequately wetted because the indicator changes only when excess fluid from the sample travels along the channel portion to the indicator means.

The presently claimed structure permits the entire sample to be punched out, as the entire sample deposition area is wetted before excess fluid travels toward the indicator means, thus eliminating the prior art problem of needing to judge the adequacy of the sample collected by eye, or use a complicated camera system that is unworkable in remote testing. In either prior art case, the entire sample is not punched out for testing, as only a portion is used, as the prior art required determining where the best concentration of the sample could be found on the absorbent paper.

Moreover, because it is excess fluid that interacts with the indicator means, the present invention is not just providing an indication of the amount of fluid collected (as in Ostrup) but rather indicates that the sample deposition portion has been adequately (or fully) wetted so as to permit excess fluid to travel. Thus, the indicator means in the present invention

AMENDMENT

U.S. Appln. No. 09/230,137

2386-1-001

indicates, by the interaction with the excess fluid sample, that there is no need (whether by eye or camera) to identify an optimum part of the sample deposition portion for punching out and onward processing.

Applicants now wish to address why the combination of Ostrup and Sangha fails to disclose or suggest the claimed invention to a person of ordinary skill in the art.

First, it is respectfully submitted that Ostrup discloses a device in which a camera is used to ascertain the best portion of the sample collection card to be used. In other words, as the sample portion is not fully wetted, a complicated structure and process is required to determine the best area from which to punch out a sample for automatic testing.

Second, it is respectfully submitted that Sangha fails to provide teachings deficient in Ostrup, so that the combination of Ostrup and Sangha fails to provide the teachings, suggestion and motivation to an artisan that would have made the present claims obvious over the teachings of the combination of references. For example, Sangha discloses that the indicator is on top of the one-way barrier, which will not provide sufficient indication as to whether an entirety of a sample has been wetted. Nor does the combination of Sangha and Ostrup disclose or suggest a channel

AMENDMENT

U.S. Appln. No. 09/230,137

2386-1-001

portion along which excess fluid sample would travel along to indicate that the entire sample deposition area has been wetted. Sangha teaches an indication that a predetermined amount of saliva has been applied to an absorbent, but does not in any way teach, suggest or motivate (in combination with Ostrup or alone) that an entire sample deposition area has been wetted, so that the automatic testing device can punch out the sample without needed to determined where on the sample area has the saliva been deposited. Applicant respectfully points out that Sangha discloses at column 11, lines 49-54 that an operator must apply the saliva to the center of the application zone, and must judge by eye whether the saliva has been supplied properly in the application zone. Thus, the combination of Ostrup and Sangha still fails to disclose the features of the presently claimed invention.

Applicant respectfully submits that in the Court of Appeals held in *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992) that:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so. Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner

AMENDMENT

U.S. Appln. No. 09/230,137

2386-1-001

suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In the present case, it is respectfully submitted that the teachings of the combination of references does not overcome the standard of establishing obviousness as exemplified in *Fritch*, as there is no suggestion from the prior art to render the present claims obvious. In fact, it is respectfully submitted that the suggestion to modify comes from Applicant's invention, not from any teachings of the references.

In light of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and a notice to that effect is respectfully solicited.

AMENDMENT

U.S. Appln. No. 09/230,137

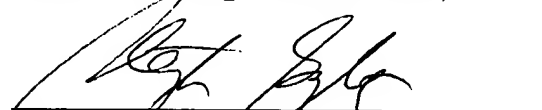
2386-1-001

. If any issues remain which may best be resolved through a telephone communication, the Examiner is requested to kindly telephone the undersigned at the telephone number listed below.

Respectfully submitted,

Date:

2/7/02



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SG\lc

Enclosure

Attorney Docket No. 2386-1-001

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COPY OF PAPERS
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
In re: the Application of

Inventors: Robert William Cunningham

Application No.: 09/230,137

Examiner: L. Cross

Filed: August 10, 1999

Art Unit: 1743

For: NEW TEST DEVICE FOR MASS SCREENING

VERSION WITH MARKINGS SHOWING CHANGES MADE

Assistant Commissioner for Patents
Box AF
Washington, DC 20231

Dear Sir:

In response to the Final Office Action dated November 7, 2001,
the Applicant requests amendment of the above-identified
application as follows:

IN THE CLAIMS:

Please amend the claims as follows:

1. (Twice Amended) A test device for use in automated testing apparatus comprising:

a substrate of size and shape suitable for handling by said automated testing apparatus, and including at least one indentation or aperture wherein said indentation or aperture is a location, size and shape suited for access by said automatic testing apparatus; and further comprising

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[supportative] supportive material mounted on at least a part of said substrate so as to be at least partially position over said indentation or aperture; and wherein said [supportative] supportive material comprises a guide means comprising a sample deposition portion that is wetted by a fluid sample, said sample deposition portion being [and] attached [thereto] to a channel portion, said channel portion including an indicator means arranged therein at a predetermined lateral distance away from said sample deposition portion for indicating that the sample portion is entirely wetted so as to be used for testing; wherein the positioning of [a] the sample to be tested on said sample deposition portion of said supportive material results in excess fluid of said sample travelling along said channel portion and interacting with said indicator means [so as to provide a measure of the adequacy of] to indicate that said sample deposition portion has been entirely wetted by the fluid sample [collected] so as to permit the excess fluid to travel along the channel portion and interact with the indicator means.